## REMARKS

The present invention relates to a stent comprising a basic structure made of a material selected from the group consisting of a biodegradable plastic material and a degradable metal, and a biodegradable shape memory polymer material (SMP) selected from the group consisting of covalent polymer networks and covalent polymer interpenetrating networks, said polymer networks **comprising pentadecalacton units**, and wherein the SMP material covers the basic structure; the invention also relates to a method of manufacturing and a method for minimal invasive implantation of such stents.

In the final Office Action of December 23, 2011, claims 1, 4-6, and 8-11 were rejected at pages 2-4 under 35 U.S.C. § 102(b), as allegedly anticipated by US 2003/0153971 (Chandrasekaran).

At pages 4-10, several rejections under 35 U.S.C. § 103(a) were posed. First, claims 3 and 15-16 were rejected over Chandrasekaran in view of U.S.P. 6,287,332 (Bolz). Second, claims 12-14 were rejected over Chandrasekaran in view of EP 1033145 A1 (Igaki). Third, claims 1, 3-6, 8-11 and 15-16 were rejected over Chandrasekaran in view of Bolz. Fourth, claims 12-14 were rejected over Chandrasekaran in view of Bolz further in view of Igaki.

In the Response to Arguments section at pages 10-11, the Examiner first noted Applicant's argument that stainless steel is not biodegradable, but the Examiner continued to rely upon US 2003/0139801 (Sirhan) for the position that stainless steel is a degradable metal, and the Examiner stated that Applicant "provides no evidentiary support that stainless steel is not biodegradable". Second, regarding Applicant arguments with respect to the Examiner's position that the Langer '084 reference disclose pentadecalacton based on Langer et al.'s disclosure of

"PDL" units, the Examiner continued to rely on Langer '084 as incorporated-by-reference in Chandrasekaran as teaching the use of pentadecalacton.

Applicant's attorney expresses appreciation to Examiner Schubert with respect to a first telephonic discussion on March 16, 2011 in which the Examiner responded to some inquiries from the undersigned attorney regarding the Office Action, and to a further telephonic discussion later that same day in which the Examiner telephoned the undersigned attorney to add to his initial comments and make note of a particular document. The Examiner has issued Interview Summary reports on these two March 16th discussions on March 30, 2011, and April 5, 2011, respectively. The substance of the matters discussed is addressed herein and in two Statement of Substance of Interviews submitted herewith.

Applicant respectfully traverses the rejections, and requests reconsideration and withdrawal thereof, particularly in view of the comments below and the further evidence submitted herewith responsive to the Examiner's position as clarified in the Office Action of December 23, 2010, and the telephone discussions noted above.

First, regarding the issue of stainless steel and how it would be considered by a person of ordinary skill in the art, and responsive to the Examiner's indication in the Office Action that Applicant should provide evidentiary support regarding the non-biodegradable characteristics of stainless steel, Applicant provides herewith such evidence, indicating the general view of those skilled in the art that stainless steel is not biodegradable.

1.) Zhang et al. "Biocorrosion properties and blood and cell compatibility of pure iron as a biodegradable biomaterial" J. Mat. Sci: Maer. Med. (2010) 21, 2151-2163.

In this publication, the biocorrosion properties of pure iron are compared to that of Mg-Mn-Zn alloy as a biodegradable material and 316L stainless steel as a biodegradable material. Please note the following passages (highlightings added):

Page 2151, right col., 2nd par.: "Compared with the first-generation inert biomaterials, such as stainless steel and titanium,..."

Page 2154, right col., last par.: "The highest corrosion potential (Ecorr) together with the highest break potential ($E_b$) was observed for 316L stainless steel, indicating the corrosion rate of 316L stainless steel is extremely low."

Page 216Q, left col., 3rd par.: "The electrochemical results in Table 2 clearly demonstrate that the corrosion rate of the pure iron in Hank's solution is two orders of magnitude higher than that of 316L stainless steel, but lower than that of Mg-Mn-Zn alloy. 316L stainless steel is widely accepted as non-biodegradable and inert biomaterials ..." (emphasis added).

2.) Rack & Qazi "Titanium alloys for biomedical applications" Mat. Sci. Eng. C 26 (2006) 1269-1277.

This paper is focused on titanium alloys for biomedical applications, especially for permanent implants such as hip implants. In the introduction, stainless steel is clearly considered as a common non-degradable material.

Page 1269, right col., 1st par.: "Various metallic materials have been used for total hip

replacements as well as other joint replacements surgeries, i.e., knees, shoulders. [...] The materials list includes stainless steel, Co-Cr-Mo alloys, titanium alloys and other more specialized alloys, e.g., Au-Pd."

3.) Long & Rack: "Titanium alloys in total joint reülacements - a materials science perspective" Biomaterials 19 (1998) 1621-1639.

This is a review on the biocompatibility and biocorrosion properties of Ti alloys. Although mentioning the enhanced corrosion resistance of titanium alloys compared to "more conventional stainless steels" (cf. abstract), stainless steel is clearly considered as a non biodegradable metal.

Page 1623, right col., 2nd par.: "Standard metallic orthopaedic materials include stainless steels, cobalt-base alloys, and titanium-base alloys [...]."

Applicant does note that, of course, as with every material stainless steel does corrode under physiological conditions to some, but a negligible extent. Specifically, the corrosion rate is so extremely small that no significant material loss occurs during the life time of a patient having a stainless steel implant. Therefore, stainless steel is widely used and accepted as a material for durable implants.

Applicant now turns to the issue of the pentadecalacton, and the assertions of obviousness by the Examiner, which rely on the Examiner's (mis-)understanding that the prior art (specifically Langer '084) used the acronym PDL to refer to pentadecalacton.

**US 2007/0129784 (Lendlein et al.)**

As to the Lendlein '784 document which was cited by the Examiner in the second phase of the Interview(s) of March 16, 2011, Applicant notes that this document has not heretofore been relied upon by the Examiner, and Applicant submits that Lendlein '784 does not appear to constitute prior art for the present application. If the Examiner disagrees, and intends to rely on Lendlein '784, the Examiner is respectfully requested to withdraw finality and issue an appropriate non-final Office Action.

**Evidence of the meaning of PDL in US 6,160,084 (Langer '084)**

The Examiner suggests/requires Applicant to provide evidence that the PDL as presently claimed is a different material *vis-à-vis* the PDL used in Langer '084.

First, it is noted that in polymeric chemistry, acronyms/abbreviations for polymers are usually voluntarily used and only for very ubiquitous polymers do commonly accepted abbreviations exist, for instance, PE for polyethylene. Anyway, such a prove is not necessary in the present case, since the intended meaning of the abbreviation PDL is clear in Langer '084, and is different from the pentadecalacton units of the present claimed invention.

In the present case, the claims do not refer to "PDL" but recite "pentadecalacton units", which has a well defined and unambiguous meaning, i.e., the group $-(CH_2)_{15}COO-$. In the specification, the abbreviation PDL is clearly used for pentadecalacton (see, e.g., pars. 0076 (containing a spelling error: *pentadeclaracton),* 0089, 0145 and the Table).

On the other hand, the meaning of PDL as used in Langer '084 is clearly defined in the Langer '084 reference itself.

In particular, PDL in Langer '084 is used to refer to multiblock copolymers containing α,ω-dihy-droxy [oligo(L-lactate-co-glycolate) ethylene oligo(L-lactate-co-glycolate)] as soft segment with the name/abbreviation PLGA200-15 (see col. 14, line 5, lines 15-25, and lines 64-67) and α,ω-dihydroxy [oligo(ethylene glycole glycolate) ethylene oligo(ethylene glycole glycolate)] with the name/abbreviation **PD**S1200 as hard segment (col. 13, lines 58-61). Thus, it is clear that in Langer `084 the abbreviation PDL is used to refer to a polymer (rather than a monomeric unit thereof) solely containing lactate units, glycolate units and ethylene glycol units.

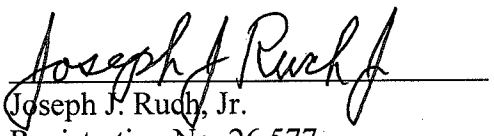
No pentadecalacton units are included in this polymer of Langer '084. Thus, Langer fails to disclose polymers containing pentadecalacton units.

In view of the above, withdrawal of the prior art rejections, reconsideration, and allowance of this application are now believed to be in order, and such actions are hereby earnestly solicited.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the local Washington, D.C. telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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